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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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SUITE 110			PAPER NUMBER	
ORANGEBURG, NY 10962-2100			1743	

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/622,974	DOERING ET AL.	
	Examiner	Art Unit	
	Neil Turk	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☒ Claim(s) 18 and 19 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/6/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Objections

Claims 18 and 19 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim may not be "according to at least one..." thus introducing improper multiple dependencies. See MPEP § 608.01(n). Accordingly, the claims 18 and 19 have not been further treated on the merits.

Specification

The disclosure is objected to because of the following informalities: The specification, on page 5, refers to claims 1 and 11 for presenting the disclosure of the invention. The specification should not reference claims to outline the disclosure of the invention, as claims may be amended or cancelled during prosecution.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 recites the limitation "filter slide" in line 1 of claim 6. There is insufficient antecedent basis for this limitation in the claim.

Claims 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 7 recites the limitation "two lasers are coupled to a first optical waveguide and/or second optical waveguide and the two optical waveguides feed the light..." It is unclear with the inclusion of "or" how the particular limitation of two optical waveguides would arise, and not a situation of one or two optical waveguides. Additionally claim 7's recitation is drawn to two lasers being included with each respective optical waveguide, for a total of four lasers in the case of two optical waveguides. Applicant's specification (pages 9-10) and drawings show two lasers, wherein only one laser is provided to one optical waveguide. Further, claim 8, dependent upon claim 7, recites limitations limited to a situation of two optical waveguides. By the inclusion of "or" in claim 7, examiner will interpret claims 7 and 8 to recite structure where only one waveguide may be required. Claim 9 is dependent upon claims 7 and 8 and therefore inherently includes the indefiniteness of the claims 7 and 8.

The term "minimum distance" in **claim 8** is a relative term which renders the claim indefinite. The term "minimum distance" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the

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invention. The term "minimum distance" renders the distance at which the optical axes of the two optical waveguides lie with respect to one another unclear.

Claim 10 recites the limitation "the detectors" in line 3 of claim 10. There is insufficient antecedent basis for this limitation in the claim.

Claims 11-15 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: claims 11-15 do not positively present any method steps; whereas the "wherein" clauses recite a semblance of a method step, these and other such clauses are not positively recited method steps and merely set forth a capability to the structural elements the clauses reference.

Claim 14 recites the limitation "the filter slide" in line 2 of claim 14. There is insufficient antecedent basis for this limitation in the claim.

Claim 11 recites the limitation "the beam splitter" in line 11 of claim 11. There is insufficient antecedent basis for this limitation in the claim.

Claims 16 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The "step 2" of claim 16 is unclear as to what

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"the boundary conditions and the correlation parameters" have in relation to steps "a)" and "b)" recite. Additionally, in claim 16, it is unclear what "the adjustment" is, as there is no antecedent basis for this term. Further, step "b)" of claim 16 is unclear as to what "a constant time interval being subtracted of the end of time window" is meant to describe or what method step it recites.

Claim 17 contains many of the above ambiguities and lack of clarity. In step "a)" of claim 17, the step should not refer to "2)" as it presently does. Additionally, step "b1)" recites "the first lifetime" and "the first amplitude", among other terms are mentioned, which have no antecedent basis. Step "b1)" also recites the terms "short", "significant proportion", "short time", among other terms which are relative terms or terms of degree that are unclear. Additionally, step "b2)" recites "beginning from time (33)", the "time" in question should be referred to by a reference numeral, it is unclear which time is being claimed and what specific limitations are associated with it.

At this time, the method steps established in claims 16 and 17 are not presented in a way in which a productive search may be done. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 18 and 19 are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility. Claims 18 and 19 are drawn to computer programs that do not contain any computer readable media.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 6, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Nelson (4,501,970). Nelson discloses a fluorometer for measuring fluorescence of samples in microtest wells (abstract). Nelson discloses that the fluorometer comprises an outer cabinet 10, support base 12, optical system 14, and a movable carriage 16 (shifted by a mechanism so as to sequentially target wells 20) for supporting a microtest plate 18 (with a plurality of wells 20) (lines 44-63, col. 3, fig. 1-4). Nelson shows in figures 3 and 4 an optical system 14, which includes an excitation source, such as an ultraviolet lamp 26, a photomultiplier 28, a pair of bi-convex lenses 30 and 32, a first pair of filters 34 and 36, a second pair of filters 38 and 40, and a mirror and optical mask assembly 42 (lines 1-6, col. 4, fig. 3 and 4). Nelson discloses light from lamp 26 is passed through aperture 84, where the rays of exciting light then diverge to lens 30, where they are refracted and pass beyond filters 34 and 36. Nelson discloses that the rays of exciting light come to the mirror and mask assembly (irradiation optic, beam

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splitter), comprised of two light-reflecting mirrors 60, 62 in a V-shaped arrangement (90° included angle), and a pair of optical masks 64, 66 (lines 20-49, col. 4, figs. 3&4).

Nelson further discloses that the excited light reflected by mirror 60 passes downward through aperture 76 to one of the sample-holding wells 20, which causes the substances in the well to be fluorescently excited and emit light which passes upwardly through aperture 76 and strikes mirror 62 (lines 1-13, col. 6, fig. 3&4). Nelson further discloses that from mirror 62 the fluorescent light is reflected towards lens 32 (emission optic) (after passing through filters 38,40), and lens 32 directs the light through aperture 94 to the photomultiplier 28 for measurement (lines 14-43, col. 6, figs. 3&4). With regards to claims 2 and 6, Nelson discloses that support blocks 82 and 90 are movable about the lens's principle axis 102, 104 so as to position the exciting light to focus more sharply on the sample wells 20 (lines 33-43, lines 67-68, col. 7, fig. 3). Examiner asserts that the mirror assembly 42 would then be movable along the principle axis so as to direct the rays of exciting light by 90° to a sample well (the light source 28 and aperture 76 such that light must incur a 90° overall deflection in order for light from source 28 to reach wells 20 through aperture 76).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson in view of Lakowicz (5,504,337).

Nelson has been discussed above.

Nelson does not disclose mirrors, which reflect 75% of the incident light and allow 25% of the incident light to pass to the mirror lying behind it.

Lakowicz discloses a light collection system, which comprise a plurality of dichroic mirrors, which pass light at predetermined wavelengths and reflect light at other wavelengths (lines 59-67, col. 9; lines 1-11, col. 10). Examiner asserts that the dichroic mirrors could be selected or have applied coatings to adjust to specifically reflect 75% of the incident light and pass 25% of the incident light.

It would have been obvious to modify the Nelson device to include dichroic mirrors, which pass light at predetermined wavelengths and reflect other wavelengths such as taught by Lakowicz so that the light reflected to the aperture for detection would only be that reflected of the desired wavelengths.

Claims 3, 12, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson in view of Veronesi (6,154,307).

Nelson has been discussed above.

Nelson does not disclose mirrors, which reflect 75% of the incident light and allow 25% of the incident light to pass to the mirror lying behind it.

Veronesi discloses a beam splitter 92 splits the beam 80 into a passthrough beam 90 (passthrough beam is incident upon component 82) and a reference beam 202 (reference beam 202 becomes incident upon detector 200). Veronesi discloses that the beam splitter splits about 99.8 percent of the beam 80 into the passthrough beam 90 and about 0.2 percent of the beam into the reference beam 202. Veronesi further discloses that the percentages at which the beam splitter divides beam 80 are related to the sensitivity of the beam detector 200 (lines 37-46, col. 8, fig. 3 and 4; columns 7 and 8).

No patentable weight is being given to the limitations that the mirrors reflect 75% of the incident light and pass 25% of the incident light. The specification does not recite any criticality to these parameters, and until such a criticality is established, it will be assumed that adjustment of the mirrors to those limitations is an obvious modification through routine experimentation in order to achieve the best results at the detector. Examiner asserts that given the sensitivity of the detector, a beam splitter could be adjusted so that 75% of the incident light is reflected and 25% of the light is passed through.

It would have been obvious to modify the Nelson device to include a beam splitter (mirrors in Nelson) such that the incident beam is divided into a passthrough beam and a reference beam (to the detector) such as taught by Veronesi in order to provide a beam splitter based on the sensitivity of the detector, which divides the incident light for proper detection.

Claims 4, 5, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson in view of Taylor (6,187,267). Nelson has been discussed above. Examiner also notes that the disclosure of Nelson includes filter elements, which allow a part of the light of the light source to pass in the direction of the sample, and as discussed above, the optical system may be movable to better focus the light on the sample well.

Nelson does not disclose a further light source.

Taylor discloses a chemiluminescence detection device that includes an analyzer with two light sources. Taylor discloses a first continuous light source 100 and a second, time-resolved light source 102 for time-resolved photoluminescence assays (col. 5&6, figs. 3-5).

It would have been obvious to include a further light source in the Nelson device such as taught by Taylor in order to provide the Nelson device with a light source for use with performing time-resolved assays.

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Claims 7-9 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson in view of Luttermann (6,713,264). Nelson has been discussed above.

Nelson does not disclose two lasers coupled to a first optical waveguide and/or second optical waveguide.

Luttermann discloses a device in which the light excites the fluorescence is passed to the substrate across at least one optical waveguide, in which two lasers of different wavelengths are enclosed in the same optical waveguide in order to excite the fluorescence (lines 7-12, col. 4; lines 25-62, col. 5, fig. 2). Examiner asserts that given one optical waveguide the limitation of the distance between optical axes is moot. Additionally, no patentable weight is being given to the minimum distance of 125 μm . The specification cites no criticality to this distance, and until a criticality is attributed to this distance, it will be considered an obvious modification to optimize the device through routine experimentation based on losses between the fibers.

It would have been obvious to modify the Nelson device to include at least one waveguide coupled to two lasers such as taught by Luttermann as an alternative passageway to direct the excitation light of multiple wavelengths to the substrate (microplate) to excite the fluorescent-excitabile samples.

Claims 7-9 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson in view of Pan (6,198,858).

Nelson has been discussed above.

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Nelson does not disclose two lasers coupled to a first optical waveguide and/or second optical waveguide.

Pan discloses a wavelength division multiplexed coupler in which two input fibers 15, 16 (optical waveguides) carrying different wavelengths from respective lasers, the optical fibers 15, 16 are then fused together (minimal separation of optical axes) and directed toward a collimator 18 (connecting lens) and then light is refocused to an output fiber 17 (lines 16-67, col. 1, fig. 1a-b). No patentable weight is being given to the minimum distance of 125 μm . The specification cites no criticality to this distance, and until a criticality is attributed to this distance, it will be considered an obvious modification to optimize the device through routine experimentation based on losses between the fibers.

It would have been obvious to modify the Nelson device to include two lasers coupled to two optical fibers which are fused together at a connecting point at a connecting lens to then have the light directed to an output fiber such as taught by Pan in order to provide a structure for combining multiple light signals from input waveguides containing signals of different wavelengths into one.

Claims 7-9 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson in view of Gorfinkel (5,784,157).

Nelson has been discussed above.

Nelson does not disclose two lasers coupled to a first optical waveguide and/or second optical waveguide.

Gorfinkel discloses a method and apparatus for identifying fluorophores.

Gorfinkel shows an embodiment for multicolor excitation and multicolor detection in figure 4. Gorfinkel discloses four lasers selected to provide the most efficient excitation of four fluorescent dyes, and the laser radiation is coupled to into four respective optical fibers. Gorfinkel discloses that the four fibers are then combined into a fiber bundle (minimal separation between optical axes), which delivers the radiation to the area of electrophoretic separation. Gorfinkel further discloses that a fiber splitter may be provided for splitting the radiation into N channels, depending on the power requirements; additionally, each fiber optic probe is provided with a fiber-transmitter for focusing the radiation on a narrow spot for fluorescence detection (lines 9-33, col. 10, fig. 4). Examiner asserts that the use of two lasers (and respective two optical fibers) would be an obvious modification based on the assay being performed. No patentable weight is being given to the minimum distance of 125 μm . The specification cites no criticality to this distance, and until a criticality is attributed to this distance, it will be considered an obvious modification to optimize the device through routine experimentation based on losses between the fibers.

It would have been obvious to modify the Nelson device to include lasers coupled to optical fibers which are then brought into a fiber optic bundle to focus radiation on a narrow observation slot such as taught by Gorfinkel in order to provide a device capable of multicolor excitation and detection and capable of focusing radiation on a narrow spot for fluorescence detection.

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Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson in view of Stumbo (6,310,687). Nelson has been discussed above.

Nelson does not specifically disclose a processor for controlling the device.

Stumbo discloses a light detection device with means for tracking sample sites that includes an incrementally movable stage, which supports sample sites to be assayed, an automated scanning mechanism, and a processor for analyzing the signal from the detector (abstract, lines 53-9, col. 7&8, claim 1).

It would have been obvious to modify the Nelson device to include a processor for controlling the device such as taught by Stumbo in order to make the device of Nelson automated and controlled.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Turk whose telephone number is 571-272-8914. The examiner can normally be reached on Mon-Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NT


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